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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Steffen GOLETZ et al.

Serial No.: 10/540,479

Group Art Unit: 1645

Filed: June 28, 2005

Examiner: Unknown

For: RECOGNITION MOLECULES FOR THE TREATMENT AND DETECTION OF TUMOURS

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

Timing and Fees

- ☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
  - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
  - ☒ before the mailing of a first substantive office action (including after filing of an RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- a final rejection under 37 C.F.R. 1.113;
  - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - a notice of allowance under 37 C.F.R. § 1.311; and

7

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

- ☐ a final action under 37 C.F.R. § 1.113;
- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);
- ☐ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- ☒ Not required by 37 CFR § 1.98.
- ☒ Copies of the materials listed are attached (except for the foregoing).

### Non-English Language References

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:
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- ☐ Translation of other relevant information on foreign search report

### Other Information

#### Payment of Fees Due (If Any):

- ☐ A check for \$\_\_\_\_\_ covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: GULDE-0063

Date: September 20, 2006

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 3

### Complete if Known

Application Number	10/540,479
Filing Date	June 23, 2005
First Named Inventor	Steffen GOLETZ et al.
Group Art Unit	1645
Examiner Name	Unknown
Attorney Docket Number	GULDE-0063

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T. <sup>2</sup>
	C1	BOEL, E. et al., "Functional human monoclonal antibodies of all isotypes constructed from phage display library-derived single-chain Fv antibody fragments," Journal of Immunological Methods, 2000, vol. 239, pgs. 153-166.	
	C2	BRECHBIEL, M.W. et al., "Synthesis on 1-(p-Isothiocyanatobenzyl) derivatives of DTPA and EDTA: Antibody labeling and tumor-imaging studies," Inorg. Chem., 1986, vol. 25, pgs. 2772-2781.	
	C3	CHOTHIA, C. et al., "The predicated structure of immunoglobulin D1.3 and its comparison with the crystal structure," Science Reports, 15 Aug. 1986, vol. 233, pgs. 755-758.	
	C4	CHOTHIA, C. et al., "Conformations of immunoglobulin hypervariable regions," Nature, 21/28 Dec. 1989, vol. 342, pgs. 877-883.	
	C5	CHOTHIA, C. et al., "Structural repertoire of the human Vh segments," Journal of Molecular Biology, 1992, vol. 227, pgs. 799-817.	
	C6	CHOTHIA, C. et al., "Canonical structures for the hypervariable regions of immunoglobulins," Journal of Molecular Biology, 1987, vol. 196, pgs. 901-917.	
	C7	HERRERA, A.M. et al., "Efficiency of erythropoietin's signal peptide for HIVmn-1 gp 120 expression," Biochemical and Biophysical Research Communications, 2000, vol. 273, pgs. 557-559.	
	C8	DAI, J. et al., "Effect of desialylation on binding, affinity, and specificity of 56 monoclonal antibodies against MUC1 mucin," Tumor Biology, 1998, vol. 19 supp. 1, pgs. 100-110.	
	C9	HINODA, Y. et al., "Circulating tumor-associated antigens detected by monoclonal antibodies against the polypeptide core of mucin: comparison of antigen MUSE11 with CA15-3," Gastroenterologia Japonica, 1992, vol. 27 no. 3, pgs. 390-395.	
	C10	JENSEN, K.B. et al., "Functional improvement of antibody fragments using a novel phage coat protein III fusion system," Biochemical and Biophysical Research Communications, 2002, vol. 298, pgs. 566-573.	
	C11	KOZAK, R.W. et al., "Nature of the Bifunctional chelating agent used for radioimmunotherapy with Yttrium-90 monoclonal antibodies: Critical factors in determining 'in vivo' survival and organ toxicity," Cancer Research, 15 May 1989, vol. 49, pgs. 2639-2644.	

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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	C12	LIAO, K. et al., "Design of transgenes for efficient expression of active chimeric proteins on mammalian cells," Biotechnol. Bioeng., 2000, vol. 73, pgs. 313-323.	
	C13	MARTIN, A.C.R. et al., "Structural families in loops of homologous proteins: Automatic classification, modeling and application to antibodies," Journal of Molecular Biology, 1996, vol. 263, pgs. 800-815.	
	C14	NUTTALL, S.D. et al., "Design and expression of soluble CTLA-4 variable domain as a scaffold for the display of functional polypeptides," Proteins: Structure, Function, and Genetics, 1999, vol. 36, pgs. 217-227.	
	C15	NYGREN, P. et al., "Scaffolds for engineering novel binding sites in proteins," Cur. Opin. Struc. Biol., 1997, vol. 7, pgs. 463-469/	
	C16	ROOMAN, M.J. et al., "Amino acid sequence templates derived from recurrent turn motifs in proteins: critical evaluation of their predictive power," Protein Engineering, 1989, vol. 3 no. 1, pgs. 23-27.	
	C17	SKERRA, A., "Engineered protein scaffolds for molecular recognition," Journal of Molecular Recognition, 2000, vol. 13, pgs. 167-187.	
	C18	STIMMEL, J.B. et al., "Yttrium-90 chelation properties of tetraazatetraacetic acid macrocycles, diethylenetriaminepentaacetic acid analogues, and a novel terpyridine acyclic chelator," Bioconjugate Chemistry, 1995, vol. 6, pgs. 219-225.	
	C19	TONYE LIBYH, M. et al., "A recombinant human scFv anti-Rh(D) antibody with multiple valences using a C-terminal fragment of C4-binding protein," Blood, 15 Nov. 1997, vol. 90 no. 10, pgs. 3978-3983.	
	C20	WU, S. et al., "Conformation of complementarity determining region L1 loop in murine IgG $\lambda$ light chain extends the repertoire of canonical forms," Journal of Molecular Biology, 1993, vol. 229, pgs. 597-601.	

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